K011547

JUL 1 9 2001

Ohmeda Medical Spot PT Lite Phototherapy System
510(k) Summary

Submitter Information

Alberto F. Profumo, RAC
8880 Gorman Road
Laurel, MD 20723-1801
Tel. (410) 888-5204
Summary prepared on April 3, 2001

Device Name(s)

Classification Name:
- Neonatal Phototherapy unit

Common Name:
- Phototherapy Lamp

Proprietary Name:
- Ohmeda Medical Spot Pt Lite Phototherapy System

Predicate Device Information

Ohmeda Medical Spot Phototherapy Lamp

Product Description

The Ohmeda Medical Spot PT Lite Phototherapy System is a phototherapy device that provides phototherapeutic light in the 400-550nm range from a metal halide bulb to the patient via a gooseneck positioned above the patient. The output spot size is adjustable from 10" to 16".

Indications for Use

The Spot PT Lite Phototherapy System provides light therapy for the treatment of hyperbilirubinemia, commonly known as neonatal jaundice, during the newborn period in the hospital.

Assessment of Technological Characteristics

The technological characteristics of the Spot PT Lite Phototherapy System are similar to those of predicate devices and do not raise new safety or effectiveness issues.

Performance Data

Since treatment of neonatal hyperbilirubinemia with phototherapy is a well established clinical practice, Ohmeda submits that clinical or animal testing to demonstrate safety and effectiveness is not necessary. The product was subject to extensive bench testing, and, to the best of Ohmeda Medical's knowledge, the requirements of 21 CFR 820, Subpart C – Design Controls – were satisfied.

Sterilization Information

The Spot PT Lite Phototherapy System is not intended to be sterilized. Cleaning and disinfecting instructions can be found in the Operations and Maintenance Manual.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2001

Alberto F. Profumo
Director of Product Assurance
Ohmeda Medical
8880 Gorman Road
Laurel, Maryland 20723

Re: K011549
Trade/Device Name: Spot PT Lite Phototherapy System
Regulation Number: 880.5700
Regulatory Class: II
Product Code: LBI
Dated: May 18, 2001
Received: May 18, 2001

Dear Mr. Profumo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011549

Device Name: Spot PT Lite Phototherapy System

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CDR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011549